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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/709,015	BANET ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/31/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 4/7/04 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a non-final Office action. The rejections under 35 U.S.C. 101 were not previously presented and were not a result of new amendments to the claims.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plastic film encasing the pressure sensitive region of the pressure-monitoring module, claimed in claim 3, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 3 recites, "wherein the pressure-monitoring module comprises a plastic film that encases the pressure-sensitive region." However, the specification lacks sufficient antecedent basis for such a plastic film.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 6 and 7 each recite, "finger-mounted component". Claim 8 recites "a wrist-mounted component". The human body or body part is considered non-statutory subject matter which cannot be positively claimed. To overcome the rejections under 35 U.S.C. 101 of claims 6 and 7, "finger-mounted component" should be replaced with "component adapted to be mounted on a user's finger" in claim 6 and "component adapted to be mounted on the finger" in claim 7. To overcome the rejection under this section of claim 8, "wrist-mounted component" should be replaced with "component adapted to be mounted on a user's wrist".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,645,154 to Oka in view of US Patent No. 6,616,613 to Goodman.

Oka teaches a blood-pressure monitoring device comprising a thin-film, pressure-monitoring module 36 comprising a pressure-sensitive region (col. 5, line 32-col. 6, line 16 of Oka), and an optical module 66 comprising an optical source 72 and an optical transmission detector 74 (col. 6, lines 33-60 of Oka). A microprocessor 28 receives and processor the information from the thin-film module 36 and the optical module 66 to determine blood pressure (col. 12, lines 61-67; col. 13, lines 14-20 and lines 45-51 of Oka). The optical source 72 generates infrared or red radiation, but Oka fails to teach the source as generating both infrared and red radiation.

However, Goodman teaches an optical module for detecting a pulse wave signal representing the volume of blood of the finger at which the module is applied, wherein the module may have employ either one or two LED's as the optical source, and wherein, when two LED's are employed, one emits red light and the other infrared (col. 8, lines 56-62; col. 9, lines 57-66; col. 10, lines 20-25; col. 32, lines 22-29 of Goodman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an infrared and a red LED in place of the single optical source of Oka,

since Goodman shows the two configurations to be functionally equivalent in detecting a pulse wave representative of blood volume.

Regarding claim 4, the optical source comprises a light-emitting diode (col. 9, lines 57-66 of Goodman).

Regarding claim 5, the optical detector comprises a photodiode (col. 9, lines 57-66 of Goodman).

Regarding claim 6, a component 70 adapted to be mounted on the finger comprises the optical module 6 (fig. 1; col. 6, lines 43-45 of Oka).

Regarding claim 8, a component adapted to be mounted on the wrist comprises the thin-film pressure-monitoring module 36 (fig. 2; col. 5, lines 41-46 of Oka).

Regarding claims 17-19, the pressure-monitoring module 36 is configured to generate a pressure waveform (figs. 3-5; col. 6, lines 14-16 of Oka). With further regard to claim 18, the optical module 66 is configured to generate an optical waveform (fig. 3; col. 6, lines 55-60 of Oka). With further regard to claim 19, the microprocessor 28 comprises computer-readable-code that processes both the optical and pressure waveforms to determine blood pressure (col. 6, lines 17-32; col. 9, line 66-col. 10, line30 of Oka).

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka, in view of Goodman, as applied to claims 1, 4-6, 8, and 17-19 above, and further in view of US Patent No. 5,467,771 to Narimatsu et al. Oka teaches using a pressure sensor including a semiconductor chip (monocrystalline silicon) and a number of semiconductor pressure-sensing elements arranged on the press surface, but fails to

further describe the pressure sensor. However, Narimatsu discloses a thin-film, pressure-monitoring module including a semiconductor chip formed of a monocrystalline silicone and comprising a pressure-sensitive region, which comprises a material 32 characterized by pressure-dependent electrical properties (col. 3, lines 33-57 of Narimatsu). The pressure-monitoring module further comprises a plastic film 78 that encases the pressure sensitive region (col. fig. 3; col. 5, lines 3-9 of Narimatsu), wherein silicone rubber is a plastic material. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pressure pulse wave sensor of Narimatsu as that in the device of Oka, as modified by Goodman, since Oka, as modified, teaches using a pressure pulse wave sensor, and Narimatsu describes an appropriate pressure pulse wave sensor.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka, in view of Goodman, as applied to claims 1, 4-6, 8, and 17-19 above, and further in view of US Patent No. 5,111,817 to Clark et al. Oka, as modified, fails to describe the housing 70 of the optical module in depth. However, Clark teaches a finger-mounted component comprising an optical module that generates both red and infrared radiation, wherein the finger-mounted component is an annular ring 34 (figs. 1 and 2 of Clark). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the housing Clark as that of the optical module in the device of Oka in view of Goodman, since Oka, as modified, teaches the optical module having housing, and Clark teaches an annular ring shaped finger component as such housing for an optical module.

Claims 9 -16 and 20 are rejected under 35 U.S.C. 103(a) as being anticipated by US Patent No. 6,544,173 to West et al. in view of Oka, and further in view of Goodman. West discloses a patient monitoring system for use in a hospital (col. 4, lines 1-2 of West), such as for monitoring patients in the Intensive Care Unit of the hospital (col. 4, lines 38-47 of West). The system comprises patient monitor 22 configured to detect and/or measure blood pressure (col. 12, lines 37-43 of West) and comprising a wireless transmitter/transceiver operating 802.11 wireless protocol (col. 13, lines 8-40; col. 16, lines 2-19 of West). West is silent as to the details of the noninvasive blood pressure monitoring device.

However, Oka teaches a continuous non-invasive blood-pressure monitoring device suitable for use in an intensive care unit (col. 1, lines 13-15 of Oka) comprising a thin-film, pressure-monitoring module 36 comprising a pressure-sensitive region (col. 5, line 32-col. 6, line 16 of Oka), and an optical module 66 comprising an optical source 72 and an optical transmission detector 74 (col. 6, lines 33-60 of Oka). A microprocessor 28 receives and processor the information from the thin-film module 36 and the optical module 66 to determine blood pressure (col. 12, lines 61-67; col. 13, lines 14-20 and lines 45-51 of Oka). Therefore, it would have been obvious to one of ordinary skill in the art to use the blood pressure monitoring device of Oka as that in the monitoring system of West, since West teaches monitoring a patient's blood pressure, and Oka describes an appropriate means for doing so. The optical source 72 of West, as modified by Oka generates infrared or red radiation, but the combined references fail to teach the source as generating both infrared and red radiation.

However, Goodman teaches an optical module for detecting a pulse wave signal representing the volume of blood of the finger at which the module is applied, wherein the module may have employ either one or two LED's as the optical source, and wherein, when two LED's are employed, one emits red light and the other infrared (col. 8, lines 56-62; col. 9, lines 57-66; col. 10, lines 20-25; col. 32, lines 22-29 of Goodman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an infrared and a red LED in place of the single optical source of West, as modified by Oka, since Goodman shows the two configurations to be functionally equivalent in detecting a pulse wave representative of blood volume.

Regarding claims 11-13, the transceiver/transmitter of the patient monitor 22 communicates with an external, secondary wireless component, comprising a long-range wireless receiver/transceiver operating 802.11 wireless protocol (figs. 1 & 2; col. 4, lines 12-31; col. 8, lines 1-17 of West).

Regarding claims 14-16, the system comprises an external, secondary wireless component, comprising a short-range wireless transceiver configured to transmit information over an 802.11 based wireless network or a GSM based network (figs. 1 & 2; col. 4, lines 12-31; col. 8, lines 1-17; col. 11, line 54-col. 12, line 6 of West).

Regarding claim 20, the short-range wireless transmitter transmits acquired vital sign information, which may include blood pressure information, to a wireless hub (figs. 1, 2; col., 12, lines 17-26 of West).

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER